HemCon ChitoFlex™-Surgical 510(k) Notification

AUG - 6 2007

5. SECTION 5 - 510(K) SUMMARY

Name and Address of Sponsor:

HemCon Medical Technologies, Inc.
10575 SW Cascade Avenue, Suite 103
Portland, OR 97223

Device Name:

Proprietary Name: HemCon ChitoFlexTM-Surgical Dressing

Common Name: Traumatic Wound Dressing
Classification Name: Dressing
Product Code: FRO

Establishment Registration Number:

9053189

General Description:

The HemCon ChitoFlex™-Surgical Dressing is a sterile chitosan based dressing intended for use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions.

It may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, donor sites, dermatalogical, etc.) and traumatic injuries.

The HemCon ChitoFlex™-Surgical Dressing is nearly identical to the legally marketed HemCon® Bandage (K043050, cleared June 3, 2005) in composition, design and processing; the only major difference is the size and the modification of the intended use for temporary treatment of severely bleeding wounds such as surgical wounds. In this respect, the indications for use are identical to the Bloxx Rapid Clotting Agent (K061722, cleared August 2, 2006).

Indication for Use:

HemCon ChitoFlex™-Surgical is intended for use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions.

It may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, donor sites, dermatalogical, etc.) and traumatic injuries.

Contact Person(s) and Phone Number:

Kevin Hawkins
Director – Quality & Regulatory
Phone (503)245.0459 x114 Fax (503)245.1326

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

HemCon Medical Technologies, Inc.
% Mr. Kevin Hawkins
Director, Quality & Regulatory
10575 SW Cascade Avenue, Suite 130
Portland, Oregon 97223-4363

AUG - 6 2007

Re: K071519
Trade/Device Name: HemCon ChitoFlex™ -Surgical Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 31, 2007
Received: June 5, 2007

Dear Mr. Hawkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

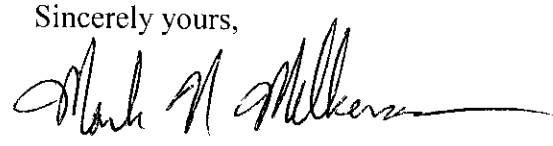
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. SECTION 4- INDICATIONS FOR USE STATEMENT

Applicant: HemCon, Inc.
510(k) Number (if known): Not Yet Assigned
Device Name: HemCon ChitoFlex™-Surgical Dressing

Indications for Use:

HemCon ChitoFlex™-Surgical is intended for use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions.

It may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatalogical, etc.) and traumatic injuries.

Prescription Use ☒ AND/OR **Over-The-Counter Use** ☐
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K071519

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(Posted November 13, 2003)